

Attorney Docket No.: **PM (DC-0251)**
Inventor: **Wade and Demian**
Serial No.: **09/720,078**
Filing Date: **July 25, 2001**
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REMARKS

Claims 1, 2, 5, and 8-17 are pending in the instant application. Claims 1, 2, 5, and 8-17 have been rejected. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Priority Under 35 U.S.C. §119(e)

Applicants acknowledge that priority to U.S. provisional patent application Serial No. 60/090,849 has been granted in light of Applicants' amendments filed 2/1/05.

II. Withdrawn Objections/Rejections

Applicants acknowledge the withdrawal of the objection under 35 U.S.C. §132 and rejections under 35 U.S.C. §112, first and second paragraphs.

III. Rejection of Claims Under 35 U.S.C. §103

Claims 1, 2, 5 and 8-17 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Anand et al. (U.S. Patent No. 6,291,208) and Heath (U.S. Patent Application No. 2002/0135722) and further view of Applicants' admission that species of classes and types of antigens are held obvious in view of one another in the instant invention.

The Examiner suggests that Anand et al. teach the use of antibody conjugates comprising antibodies that bind antigen presenting cells, including dendritic cells, to deliver antigens in order to generate immunogenic compositions to a variety of

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antigens and that this is applicable to any antigen derived from viruses, bacteria and tumors.

It is further suggested that Heath teaches the co-administration of a CD40 stimulating moiety (e.g., anti-CD40 antibodies) and the appropriate antigen, including the use of covalent linkage or co-entrapment as a vaccine to a variety of antigens.

Thus, the Examiner suggests that prior art teaches all three components of the composition used in accordance with the method of the invention. It is suggested that adjuvants are substances that enhance or potentiate the immune response to an antigen and that Heaths that CD40 stimulators can enhance antibody response to pneumococcal polysaccharides in individuals unable to respond to polysaccharide only-based vaccines. It is therefore, suggested that there would be a reasonable expectation of success in producing an immune response greater than the simple sum of antibody-antigen conjugates and anti-CD40 antibodies acting alone. The Examiner suggests that given the teachings of Heath to provide anti-CD40 with antigen in composition form or as a conjugate and the teachings of Anand et al. to provide antigen with anti-antigen present cell/dendritic cell antibodies, it would have been obvious to one of ordinary skill in the art to administer the antigen in the context of such antigen-antibody conjugate with the immunostimulatory anti-CD40 antibodies to boost the immune response to a wide variety of desired antigens, including providing both components in the same compositions, as taught by Heath. It is further suggested that one of ordinary skill would have been motivated to target professional antigen presenting cells such as dendritic cells with the combination of

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antigen-antibody targets and the immunostimulatory agonistic CD40 antibodies to enhance the immune response to a wide variety of antigens. Applicants respectfully traverse this rejection.

MPEP 2143.01 indicates that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Anand et al. specifically teach at column 3, lines 3-5, that “[o]ne feature of the present invention is the ability to obtain an enhanced immune response to an antigen without the use of an adjuvant.” From this passage and the disclosure as a whole, in particular column 9 which discusses vaccine preparation and use, it is clear that Anand et al. do not contemplate the use of an adjuvant in combination with antigen-antibody conjugate disclosed therein.

In contrast, Heath specifically identifies CD40 ligands as adjuvants for eliciting an immune response to antigens (see paragraphs 0044-0046).

Accordingly, there would be no motivation to modify the teachings of Anand et al. to routinely include a CD40 adjuvant of Heath, because Anand et al. fail to suggest the desirability of the combination in stating that an enhanced immune response is obtained “without the use of an adjuvant”. Thus, the suggestion or motivation to modify Anand et al. or to combine the referenced teachings is lacking and therefore the claimed invention is not obvious in accord with the requirement set forth in MPEP 2142. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

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IV. Conclusion

The Applicants believe that the foregoing comprises a full and complete response to the Advisory Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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